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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,277	12/04/2001	Thomas J. Maginot	1537-0022	6800

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EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/005,277	MAGINOT ET AL.	
	Examiner	Art Unit	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-65* is/are pending in the application.

4a) Of the above claim(s) *32,47 and 65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-31,33-46 and 48-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 March 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/04/02, 01/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of D for species I, 5 for species II, and aa for subspecies in the reply filed on March 26 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 32, 47, and 65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 26 2007. Applicant has indicated that claims 17-65 are readable on the elected combination of species and subspecies. However, claims 32, 47, and 65 are not seen to be readable on the elected combination. Therefore, claims 32, 47, and 65 have been withdrawn.

Information Disclosure Statement

3. Part of the information disclosure statement filed October 4 2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the IDS form lacks the title, date, and pertinent page numbers of the two non-patent literature documents, which have been crossed out, and have thus not been considered. Also, U.S. Patent No. 5,272,527 has not been considered because it appears to be in error as it pertains to a picture image monitoring system and the inventor is Watanabe and not Schatz et al. It has been placed in the application file, but the information referred to therein has

not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The phrase "which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56" should not be used in the declaration and should be replaced with "which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56".

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 911. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or

amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to because it appears that reference character 67 in Figure 46 should be replaced with reference character 64. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If

the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The abstract of the disclosure is objected to because the abstract is too long. Correction is required. See MPEP § 608.01(b).

8. Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarity the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. Both paragraphs on pages 1 and 2 need to be updated.

Appropriate correction is required.

9. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose a guide catheter assembly having a proximal fluid lumen orifice, a distal fluid lumen orifice, and a first fluid lumen extending therebetween and having a first opening and a second opening where both

openings are spaced apart from the distal fluid lumen orifice. The specification also fails to disclose a second catheter defining a second fluid lumen and being at least partially positioned within the guide catheter assembly and extending through and between the first opening and the second opening. The specification fails to disclose a proximal segment of the second catheter being positioned outside of the guide catheter assembly and being proximal to the second opening and a distal segment of the second catheter being positioned outside of the guide catheter assembly and being distal to the first opening. The specification fails to disclose the tissue growth member being spaced apart from the second catheter and defining a central passage though which the second catheter extends. The specification fails to disclose a passage extending between the first opening and the second opening where the second catheter is located within the passage, the passage is isolated from fluid communication with the first fluid lumen, and the second fluid lumen is located within the passage. The specification fails to disclose the guide catheter assembly including a first coupling and the second catheter including a second coupling. The specification fails to disclose the second catheter (assembly) having a proximal fluid lumen port, a distal fluid lumen port, and the second lumen extending therebetween and the distal fluid lumen orifice of the guide catheter assembly being located distal to the distal fluid lumen port. The specification also fails to disclose a guide catheter assembly having a proximal fluid lumen orifice, a distal fluid lumen orifice, an internal passage, a first opening and a second opening where both openings are spaced apart from the distal fluid lumen orifice. The specification fails to disclose a second catheter extending through the first and second openings, defining a first fluid

lumen and having a first segment and a second segment. The specification also fails to disclose the guide catheter assembly defining a second fluid lumen and the second fluid lumen being spaced apart from the distal fluid lumen orifice. The specification fails to disclose the second catheter having a third segment where the third segment is positioned outside of the guide catheter assembly and proximal to the second opening.

10. The disclosure is objected to because of the following informalities: There appears to be a grammatical error in line 13 of page 11.

Appropriate correction is required.

Claim Objections

11. Claims 31, 46, and 64 are objected to because of the following informalities: Claims 31, 46, and 64 recite the limitation "said second catheter assembly" in line 2. There is insufficient antecedent basis for this limitation in these claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 17-20, 23-25, 30, 31, 33-35, 38-40, 45, 46, 48-53, 56-58, 63, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Uthmann (U.S. Patent No.

4,385,631). Uthmann discloses a catheter system (10) having a guide catheter assembly and a second catheter (11). In Figures 3 and 4, Uthmann shows the guide catheter assembly with a proximal fluid lumen orifice(18), a distal lumen orifice, and a first fluid lumen (12) and having a first opening and a second opening spaced apart from the distal fluid lumen orifice. In Figures 2 and , Uthmann shows the second catheter defining a second fluid lumen and being at least partially positioned within the guide catheter assembly and extending through and between the first and second openings. A proximal segment of the second catheter is positioned outside of the guide catheter assembly and proximal to the second opening and a distal segment of the second catheter is positioned outside of the guide catheter assembly and distal to the second opening (see Figure 1). A passage (13) extends between the first and the second openings and is isolated from the first fluid lumen (12). The second fluid lumen of the second catheter is located within the passage (13). The catheter system includes couplings (26, 27). The second fluid lumen of the second catheter extends between a proximal fluid lumen port (shown adjacent to 28) and a distal fluid lumen port (shown at 20). The distal fluid lumen orifice of the guide catheter assembly is located distal to the distal guide lumen port of the second catheter as the second catheter is being inserted into the second opening of the guide catheter assembly. As to claim 48, the guide catheter assembly has a proximal fluid lumen orifice (18), a distal lumen orifice, an internal passage (13), a first opening and a second opening where the first and second openings are spaced apart from the distal fluid lumen orifice and the second catheter extends through the first and second openings, defines a first fluid lumen and has a first

segment and a second segment. The first segment is located within the internal passage (13) and the second segment is positioned outside of the guide catheter assembly and distal to the first opening (see Figure 1). The guide catheter assembly defines a second fluid lumen (12) which is spaced apart from the internal passage. A third segment of the second catheter is positioned outside of the guide catheter assembly and proximal to the second opening.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 21, 22, 26-28, 36, 37, 41-43, 54, 55, and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uthmann in view of Amarasinghe (U.S. Patent No. 4,936,826). Uthmann discloses the catheter system substantially as claimed. However, Uthmann is silent on the system including a tissue ingrowth member secured to an outside surface of the guide catheter assembly and being spaced apart from the second catheter. Uthmann is also silent on the guide catheter assembly including a first locking component and the second catheter including a second locking component where the first and second locking components are configured to lock the second catheter to the guide catheter assembly. Amarasinghe discloses a catheter system having a guide catheter assembly (11) and a second catheter (15) where a tissue

ingrowth member (19) is secured to an outside surface of the guide catheter assembly and spaced apart from the second catheter and where the guide catheter assembly includes a first locking component (12) and the second catheter includes a second locking component (16). The tissue ingrowth member (19) defines a central passage and the second catheter extends through the central passage. The first and second locking components are configured to lock the second catheter to the guide catheter assembly. The first locking component (12) includes a set of threads which mate with an internally threaded cap of the second locking component. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the outer surface of the guide catheter assembly of Uthmann with a tissue ingrowth member as taught by Amarasinghe as both Uthmann and Amarasinghe teach using catheter systems having a guide catheter assembly and a second catheter for hemodialysis and Amarasinghe teaches that it is well known to use a tissue ingrowth member to allow the guide catheter assembly to be sealingly attached to a patient's body. To provide the catheter system of Uthmann with locking components as taught by Amarasinghe would also have been obvious to one having ordinary skill in the art at the time the invention was made as Amarasinghe teaches that it is well known to lock the second catheter to the guide catheter assembly in a catheter system which is being used for hemodialysis.

16. Claims 29, 44, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uthmann in view of Taussig (U.S. Patent No. 5,261,416). Uthmann discloses the catheter system substantially as claimed. However, Uthmann is silent on

a valve being positioned within the guide catheter assembly and in contact with the second catheter. Taussig discloses a catheter system having a guide catheter assembly (22) and a second catheter (23) where a valve (66) within the guide assembly and in contact with the second catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the guide catheter assembly of Uthmann with a valve within the guide catheter assembly and in contact with the second catheter as taught by Taussig as Taussig teaches that it is well known to provide a valve for sealing the distal end of a guide catheter assembly for prevent fluid from entering the distal end of the guide catheter assembly.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER